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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/622,470 | 07/21/2003 | Debbi Drane | 017227-0190 | 4517 |
| 22428 7590 12/14/2007 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007 | | | | |
| | | | EXAMINER LI, BAO Q | |
| | | | ART UNIT 1648 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|-------------------------------|------------------------------|--|
| Office Action Summary | Application No. 10/622,470 | Applicant(s) DRANE ET AL. | |
| | Examiner Bao Qun Li | Art Unit 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 44-99 is/are pending in the application.
- 4a) Of the above claim(s) 56-63, 77-83 and 86-99 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 44-55, 64-76, 84 and 85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>10/03/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The amendment and response filed on Oct. 11, 2007 have been acknowledged. Claims 1 and 64 have been amended. Claims 2-43 were canceled. Claims 1, 44-99 are pending before the examiner. Claims 56-62, 77-83 and 86-99 were withdrawn from consideration. Claims

Claim Rejections - 35 USC § 112 withdrawn

1. Applicant's arguments, see response, filed on Oct. 10, 2007, with respect to the new matter rejection have been fully considered and are persuasive. The rejection of the new matter has been withdrawn.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1, 44, 46-55, 64-76 and 85 (Occurred in typographic error as 86 in the previous office action) are rejected under 35 U.S.C. 102(b) as being anticipated by Simmonds et al. (A)

(WO 94/25602A1) or under 35 U.S.C. 102(e) as being anticipated by Simmonds et al. (B) (US Patent No. 6,881,821B2) or by Simmonds et al. (C) (US 7,198,892B2) in light of the teaching by Sjolander et al. (**Advanced Drug Delivery Reviews** Volume 34, Issues 2-3, December 1998, Pages 321-338).

4. In the response, Applicants argue that Simmonds A-C only teach that HCV peptide may be attached to a particular structure, such as liposome or ISCOMS. This teaching cannot anticipate the present invention because it only suggests "attaching" the peptide on an ISCOM, not preparing an electrstatically complex. There is no teaching and suggestion forming an electronic association between the peptide and ISCOM via ionic bond, or electronic means. Applicants further submit that as of the 1994 filing date of Simmonds (A) to (C)., those skill in the art would have understood the teaching of peptides attached to a particular structure, such as liposome or ISCOMS", "to implicate a non-ionic bond in between the peptide and the organic complex. Applicants therefore, allege that Simmonds et al. fail to teach a complex or composition meeting every limitation of the rejected claims.

5. Applicants' submission has been fully considered; however, it is not found persuasive. In the instant case, the composition or complex of Simmonds et al. comprises a negative charged organic complex liposome or ISCOM and a positive charged antigen. Thus, the composition of Simmonds is the same as the claimed composition. The only deficiency noted in the references of Simmonds et al. is that Simmonds et al. do not define that the negative charged organic complex liposome or ISCOM and a positive charged antigen are associated by an electrostatic interaction. However, this deficiency or silence does not render the claimed invention patentable. The composition or complex of Simmonds et al. comprises a negative charged organic complex and a positive charged antigen. General chemistry alone can assure that the charges will attract one another. Thus, while the electronic interaction between the negative charged organic complex and a positive charges antigen are not stated by Simmonds et al. the electronic interaction between the two charges are inherently presented in the composition of Simmonds et al. is inherently existed based on the general chemistry, in that the two charged are attracted to one another to form the necessary electronic interaction. Applicants are reminded that inherency anticipation by Simmonds et al. does not need expressively teach that the negative charged

organic complex and a positive charged antigen are associated by electronic interaction to anticipate the claimed invention.

6. Regarding the limitation of “the electrostatically association” because the claimed product having same structure, the biological activity own by a structurally same product is inherent. See In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) [PTO can require an applicant to establish that a prior art product does not necessarily possess the characteristics of the claimed product when the prior art and claimed products are identical or substantially identical.

7. Regarding the argument that by 1994 when the Simmonds’s references were filed, a person skill in that art would not implicate that the negative peptide attaching to the ISCOM or liposome as an ionic-binding, applicants’ attention is directed to Feit et al. (2003, J. Pat. Trade. Off. Soc., Vol. 85, No. 1, pages 5-21), in that article, Feit et al. teach three criteria for analysis whether the prior art is inherently anticipate a claim(s). (1). The most important criterion is certainty. Citing *In re Tomlinson* and *In re Zierden*, Feit et al. state that certainty is established when the reference process necessarily **results** in the claimed process as opposed to a **possibility**. (2) The second criterion is chronology; it will always happen. Feit et al. state that the chronological test is forward chronology. Citing *Eli Lilly and Co. v Barr Laboratories, Inc.*, Feit et al. argue that the claimed result must always be obtained based upon the prior art method. 3) The third criterion is the legal standard. Feit et al., citing *Continental Can*, state that the legal standard is whether the missing descriptive material would be so recognized by a person of ordinary skill in the art as necessarily present in the thing. It is irrelevant whether the identified characteristic at the time of filing the application is in question, or first becomes apparent at a later time. In the instant case, The composition or complex of Simmonds et al. comprises a negative charged organic complex and a positive charged antigen. General chemistry alone can assure that the charges will attract one another. Thus, while the electronic interaction between the negative charged organic complex and a positive charges antigen are not stated by Simmonds et al. the electronic interaction between the two charges are inherently presented in the composition of Simmonds et al. is inherently existed based on the general chemistry, in that the two charged

are attracted to one another to form the necessary electronic interaction regardless it was identified or not.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1, 44-55, 63-76 and 84-85 are still rejected under 35 U.S.C. 103(a) as being unpatentable over Simmonds et al. (A) (WO 94/25602A1) or (B) or (C) as cited above in view of the teaching by Cerny et al. (J Clin Invest. 1995 Feb;95(2):521-30).

10. In response to the rejection, Applicants submit that inability of Simmonds A-C to teach or suggest that the claimed invention is shown above. While Cerny is cited teaching HCV T cell epitopes, Cerny does not resolve the inability that Simmonds et al. teach or suggest the claimed immunogenic complex comprising a negative e charged organic complex and a positive charged antigen, wherein the organic charged complex and the antigen are electronically associated.

11. All of Applicants' submission has been considered; however, it is not found persuasive for the reasons set forth in the paragraphs 4-6 of this office action. Hence, the rejection is maintained.

New Ground Rejection:

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1, 44, 46-51, 55, 64-65, 67-72, 75 are rejected under 35 U.S.C. 102(b) as being anticipated by Garcon et al. (WO 96/33739A1)
14. Garcon et al. disclose an immunogenic composition comprising an antigen, immunogenic active saponin, cholesterol, and MPL (Claim 1-6), wherein the immunogenic active saponin, cholesterol, and MPL are the components constituted in the immune stimulatory complex (ISCOM), which is negatively charged organic complex. Therefore, 1, 44, 46-51, 55, 64-65, 67-72, 75 are inherently anticipated by Garcon et al.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bao Qun Li
Dec. 4, 2007.

Baoqun Li
Baoqun Li, MD
PATENT EXAMINER
Dec. 4, 2007